No. 20995

In the

United States Court of Appeals

For the Ninth Circuit

GLYNN RICHARD DAVIS and
FLORENCE DAVIS, husband and wife,

Appellants,

v.

WYETH LABORATORIES, INC., a New York corporation, and AMERICAN HOME PRODUCTS CORPORATION, a Delaware corporation,

Appellees.

APPELLANT'S REPLY BRIEF

On Appeal from the District Court of the United States for the District of Idaho, Southern Division

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APPELLANT'S REPLY BRIEF

Our reply brief is divided into two parts. In the first part we answer Appellees' response to all of our causes of action except failure to warn. In the other section we discuss their response to our arguments on failure to warn.

I.

ALL CAUSES OF ACTION EXCEPT FAILURE TO WARN

With respect to the various drug products manufactured in this country relating to the human body, there is an

easy classification of uses. The cases cited by Wyeth relate to pharmaceutical uses not involved in this case. The catagories are:

I. PRODUCTS THAT ARE USED FOR COSMETIC PURPOSES.

This gives rise to a type of case in which the hair falls out, fingernails are disfigured, and so on in the use of cosmetic products. *Rogers vv. Toni Home Permanent*, 147 N. E. 2d 612 (Ohio 1958). Nonprescriptive, over-the-counter products are involved that harm hypersensitive or idiosyncratic plaintiffs. Some courts have granted relief; some have not. As pointed out in *Sterling Drug v. Cornish,* 370 F.2d 82 (C.C.A. 8th 1967) the denial of relief seems to be based on the unforseeability of the injuries and the futility of a warning, or the lack of an allergic class.

II. PRODUCTS CONSUMED TO IMPROVE THE HEALTH OF AN INDIVIDUAL.

These cases involve drugs such as MER-29, taken to reduce the cholesterol in the bloodstream, but additionally cause cataracts in the eyes. *Cudmore v. Richardson-Merrill, Inc.*, 398 S.W.2d 640 (Texas 1966). Or Aralen, a drug effective in the treatment of arthritis but that can additionally destroy the retina of the eye. Given on prescription, the drugs are to correct a patient's difficulty and involve a medical decision as to whether the cure is worth the risk.

III. PRODUCTS CONSUMED TO PREVENT DIS-

EASE IN AN INDIVIDUAL BUT NOT IN OTHERS.

IV. PRODUCTS CONSUMED TO SUPPRESS DISEASE IN AN INDIVIDUAL AND IN OTHERS.

This is the catagory in which Sabin polio vaccine falls. It has several factors not found in other cases. These are: communicable disease, mass clinic in which a prescription drug was given to a healthy individual without a prescription, the public was induced to take a vaccine to eliminate a disease.

Wyeth having deprived us of our strict liability theory below, now seeks to have it reinstated on appeal on the theory that an instruction on warranty of merchantability is an instruction on strict liability in tort. Instruction No. 14, requested by Wyeth, says that the warranty involved in this case "is that the Sabin vaccine was reasonably fit and reasonably safe for consumption by members of the public as a whole."

Strict liability in the classic definition is:

> "A manufacturer is strictly liable in tort when *an article* he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that *causes injury to a human being." Greenman v. Yuba ~~Pines~~ Powen Products, Inc.*, 377 P.2d 897 (Cal. 1963). Emphasis supplied)

Warranty of merchantability relates to the public as a whole. Strict liability relates to the individual.

Wyeth argues that the fact their products gave the plain-

tiff polio does not demonstrate a defect. The defect was amply explained by doctors Ager and Ravenholt. (Appendix A) Logic dictates that a vaccine which produces the very disease it is designed to prevent is by definition defective. Additionally, plaintiff's experts testified that Type III Sabin vaccine is pathogenic and this was the cause of the disease. This is sufficient. *Gottsdanker v. Cutter Laboratories*, 6 Cal. Rep. 320, 79 A.L.R. 2d 290 (Cal. 1960); *Stromsodt v. Parke-Davis and Company*, 257 F. Supp 991 (N. D. 1966); *Brown v. Globe Laboratories*, 84 N. W. 2d 151 (Neb.).

The theory as to why it causes the disease is that of the so-called "hot particle". (See Appendix B)

Further comment on the Wyeth strict liability argument requires a look at the instructions. Only three related to liability. Instructions No. 13, 14 and 15 are set out in full in appendix. (See Appendix C)

Instruction No. 14, as given by the court, was an instruction that was requested by the defendant. Apparently, Wyeth is interested in esablishing in this case that it is a complete defense in the sale of its polio vaccine if it meets the warranty of merchantability, that is, if it is reasonably safe for consumption "by members of the public as a whole". (Instruction No. 14) At best, the instruction is very confusing. In Instruction No. 13, the court discusses implied warranty, and in it the court says that if Glynn Davis contracted polio as a result of taking the defendants' vaccine, then defendant has breached its implied warranty. Then, in Instruction No. 14, the court turns around and says in considering the question of breach of

implied warranty, the vaccine is reasonably fit for the particular purpose for which it was manufactured if it is reasonably safe for consumption by members of the public as a whole. Instruction No. 14, following Instruction No. 13, would obviously be read by the jury as a modification or limitation of the scope of the implied warranty defined in Instruction No. 13. In effect, it reduced the statement of the law of implied warranty to a statement that the manufacturer is not liable even if he causes the disease his product was intended to prevent if it was reasonably fit "for the public as a whole", Thus, the only legal theory submitted to the jury was a warranty of merchantability. Davis, in the trial below, could recover on only one ground, that is, that the vaccine was not reasonably fit for the public as a whole. Whether it was fit for the public as a whole was left to the jury with no definitions, illustrations or explanation of terms to guide them. Did the instructions mean that plaintiff could recover only if he proved that 51% of those taking the vaccine contracted polio? The jury could have understood that to be the import of the instructions.

In Instruction No. 15, requested by the defendants, the court says that in order to find for us we must have proved that the plaintiff is suffering from paralytic poliomyelitis, that he contracted this disease from the defendants' Type III Sabin vaccine, and that he contracted the disease as a breach of the warranty of fitness, if any, on the part of the defendant.

Nowhere is an implied warranty of fitness defined. If you look at the preceding instruction (Instruction No. 14) and try to determine what an implied warranty of

fitness is, you have to conclude that it means the vaccine was reasonably safe for consumption by members of the public as a whole. Again what is meant by "reasonably safe for consumption by members of the public as a whole" is not defined, nor what is meant by the statement that the "vaccine could be used with absolute safety". Instead, the entire matter is left to the discretion of the jury. This state of confusion resulted in the verdict for the defendant. Wyeth has attempted to take these confusing instructions and turn the only issue that could possibly be construed as having been submitted to the jury, that is, an implied warranty of merchantability into an instruction on strict liability, which it is not.

The various cases relied upon by the defendant in support of its theory that it should not be liable for an implied warranty of fitness are not apropos to our situation. There is only one case decided in the United States to our knowledge in which the issue of implied warranty of fitness for the intended purpose of the drug was raised. That case was the renowned decision in *Gottsdanker v. Cutter Laboratories*, 6 Cal. Rep 320 (Cal. 1960), 79 A.L.R. 2d 290. Recovery was permitted on this cause of action as well as on a cause of action involving an implied warranty of merchantability. The various courts in discussing implied warranty and permitting a recovery based thereon , particularly in the drug field, have confused the two warranties. The court in the Cutter case pointed out that the defendant's vaccine contained live and active poliomyelitis virus. Thus the vaccine was not wholesome; it was neither merchantable nor fit for its intended purpose. The difference between the two warranties is vital.

(See Appendix D) A merchantable warranty applies to the public as a whole. The manufacturer then asserts if it is reasonably fit for the public, he is not liable to the individual. A fitness warranty runs to the individual. The manufacturer warrants that the drug is fit for the individual who consumes it. He warrants that in this particular individual the drug will not cause the disease it is warranted to prevent. In the allergic reaction cases, the implied warranty of fitness is not extended to the individual because he is a member of an abnormal group. Appellees make no claim that Davis is in an abnormal group. They ask the court to reason that if a vaccine produces only a few cases of the disease it is designed to prevent, there is no liability on the manufacturer. In this action, Wyeth asserts as a matter of defense that it need only show that its product was safe for most members of the public. If so, they owe no further duty to their customers. They thus claim that they do not warrant that an individual will not get polio from their product. The cases they cite do not so hold.

The first is *Cornish v. Sterling Drug, Inc.*, 370 F.2d 82 (C.C.A. 8th 1966). The case involved a drug called Aralen, used to treat arthritis. Over a long period of use (four years) it caused blindness. Recovery was allowed the plaintiff in that the company failed to warn the doctor prescribing the drug of its danger. In our case, Wyeth failed to warn the volunteers and the druggist who gave the vaccine of the risk or danger well known to defendant but unknown to plaintiff. The trial court had found that implied warranty of fitness was not involved as the drug was fit to treat arthritis. The drug itself did do what

it was intended to do to the person who purchased it. In the case of *Lewis v. Baker*, 413 P.2d 400 (Ore. 1966) the person who took MER-29 had side effects.

The same is true of the earlier Oregon case of *Cochrane v. Brooke*, 409 P.2d 904 (Ore. 1966). In each case there was a question of whether or not an isolated reaction would breach a warranty of merchantability. In each case the court said no. Neither case involved a warranty of fitness for the intended purpose of the drug. As a matter of fact, in this respect, the MER-29 drug was fit for the purpose it was intended. Its purpose was to reduce cholesterol in the bloodstream. It did do this. It also, however, caused side effects. The drug company did not warrant that it would not cause side effects; it simply warranted that it would reduce cholesterol. These cases would be more analagous to our case if the drug had increased cholesterol in the bloodstream resulting in a heart attack.

The only other case they cite in connection with this matter is *Cudmore v. Richardson-Merrill, Inc.*, (supra). Again this is a MER-29 case with the additional factor that at the time the plaintiff in that case took the drug, apparently the manufacurer didn't know that it did cause side effects.

None of the cases relied upon by defendant support defendant's contention that a drug manufacturer is not liable to a consumer of the product who contracts the malady the product was intended to prevent as a direct result of his consumption of the product. To the contrary, in such case, the manufacturer is held liable because the product is not fit for the purpose intended. *Gottsdanker v. Cutter*

Laboratories, 6 Cal. Rep. 320, supra.

FAILURE TO WARN

In its reply to plaintiff's position that the cause of action of failure to warn should have gone to the jury, Wyeth cites a number of allergy cases in defense of its position that it need not warn. The cases cited are those in which it was unknown that a reaction would occur and there was no class of persons to which it would be applicable. The rationale of the rule seems to be that the allergy, not the product, causes an unforseeable harm. This is certainly not the situation in the instant case. The risk and harm and persons to be paralyzed by Sabin III were well known by Wyeth before its product was fed to Davis. (Of interest in this connection, see Carter, *Breakthrough* (1966), Library of Congress Catalog Number: 65-26621, in particular, Chapter 16). Davis took the Wyeth company's Type III vaccine in March 1963.

On September 15, 1962, the Surgeon General's Oral Poliomyelitis Vaccine Advisory Committee met in Washington, D. C., and reviewed the occurrence of polio cases after the administration of the vaccine.

On September 20, 1962, the United States Surgeon General issued a report (Plaintiff's Exhibits 9 tnd 11) explaining the results of the meeting.

Further findings were made:

> "Of the reported cases to date, 1 following Type I vaccine and 11 following Type III vaccine were considered by the Committee to be clinically consistent

with paralytic poliomyelitis and with laboratory findings which could not exclude a possible relationship to the administration of oral vaccine."

The risk was estimated:

"The incidence, assuming all cases to have been vaccine induced, is but 11 cases among more than 13 million fed. This is less than one case per million doses given. When the risk is related to age it is apparent that adults are exposed to a greater hazard than are children. Inadequate information on the age specific vaccine acceptance rate, however, makes it impossible to calculate a more precise estimate of the risk at this time."

Recommendations were made:

"With the incidence of poliomyelitis at a low level in this country, the Committee therefore recommeneded that the Type III vaccine be restricted to preschool and school age children and to those adults in high risk groups such as those traveling to hyperendemic areas or in areas where a Type III epidemic is present or impending."

The Surgeon General further stated:

"Present data indicate that for 1962, the paralytic poliomyelitis rate for those under 20 will be approximately 7.6 per million; for those over 20, about 0.9 per million. These rates will represent a record low for the 52-year period since the reporting began."

The report of the Special Advisory Committee on Oral

Poliomylitis Vaccine to the Surgeon General of the Public Health Serevice of July 17-18, 1964, pointed out that the incidence of paralytic poliomyelitis declined from an annual level of 14.6 cases per 100,000 in the 5-year period from 1953 to 1957 to a rate of approximately 1.8 for the period 1957 to 1961. They pointed out that this decrease of 88% was largely attributable to the use of inactivated poliomyelitis vaccine (Salk) (Plaintiff's Exhibit 11).

Since 1961 the incidence has declined further; the paralytic case rate for 1963 was 0.2 per 100,000. The Committee pointed out that from 1955 through 1961 400,000,000 doses of inactivated poliomyelitis vaccine were distributed in the United States. A high proportion of the children and more than one-half of the adults in the population received one or more injections of the vaccine. In 1962, 36,000,000 doses were distributed, and in 1963 the amount declined to 19,000,000 doses. Fortunately for the public, most persons were immunized against polio by Salk vaccine before taking the dangerous Sabin product. Some were not. Dick Davis was one of the unfortunates. Were it not for the previous administration of Salk vaccine, the incidence of vaccine induced polio would have been much greater.

The defendant's argument that the plaintiff in this case only had one chance in 2½ million of acquiring polio when he took their vaccine in 1963 ignores the fact that in Montana in 1963, there were no reported cases of polio. In 1964, there were no reported cases; and in 1965, there were no reported cases (Plaintiff's Exhibit 13, Tr. 352). The plaintiff's polio case was recorded as being from the state of Idaho. The chances of the plaintiff not getting

polio if he had stayed in Montana and not taken the defendant's drug were 100%. Whereas, by taking the defendant's drug, he had a 100% risk of getting the disease. (Dr. Ravenholt's testimony, Tr. 495).

In December 1962, again some months before Mr. Davis bought the Wyeth product that gave him the disease, the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccine issued another report. This one was dated Decembed 18, 1962 (Plaintiff's Exhibits 10 and 11). The Committee found:

> "On the basis of data now available, the total number of cases associated in time with the direct administration of Type III vaccine and considered by a committee majority as 'compatible' is now 11, of which 8 are over 30 years of age."

The Committee recommended:

> "It is therefore recommended: (1) that community plans for immunization be encouraged, using all three types, and (2) that immunization be emphasized for children in whom the danger of naturally occurring poliomyelitis is greatest and who serve as the natural source of poliomyelitis infection in the community. Because the need for immunization diminishes with advancing age and because potential risks of vaccine are believed by some to exist in adults, especially above the age of 30, vaccination should be used for adults only with full recognition of its very small risk. Vaccination is especially recommended for those adults who are at higher risk of naturally occurring disease; for example, parents of young children, pregnant women, persons in

epidemic situations and those planning foreign travel."

Doctor Langmuir, a member of the 1962 and 1964 Surgeon General's Committee testified as to the risk in 1962:

> "I think what I said before, that rural persons are more likely to be susceptible to polio than those having an urban background; upper class persons more likely than lower class persons based, we believe, on the risk or opportunity of prior exposure to wild polioviruses. So a person who is likely to be more susceptible, with freedom of past experience, exposed to a risk that would be more likely to develop the disease after such exposure than a person who was immune." (Tr. 369, L. 11-19)

Doctor Ager, a member of the Surgeon General's Committee in 1964 testified as to the known risk in 1962:

> "My opinion of the risk was and is that it is somewhere in the neighborhood of one in two or three hundred thousand vaccinations of adult males." (Tr. 517, L. 15-18)

Consequently, it was well known in 1962 that Sabin vaccine caused polio. Plaintiff's evidence showed the people who would probably contract polio from taking Sabin vaccine were in the following categories: (1) those who had no Salk shots; (2) males over 30 years of age; (3) those residing in non-epidemic areas and rural areas; (4) those in the upper socio-economic group; and (5) those residing in the Pacific Northwest. This information should have been divulged to people purchasing Wyeth products. The company knew that its product would cause the dis-

case it was supposed to prevent in certain persons. Wyeth even knew mathematically how many would get the disease. Moreover, for those persons over 30 in whom there was a risk, there was a perfectly safe, reliable product that could be taken to immunize. That was Salk vaccine. Doctor Alexander Langmuir, heretofore quoted, is one of the truly great pioneers in the field of medicine. At the time of taking his deposition, Doctor Langmuir was Chief of the Communicable Disease Center, United States Public Health Service. As a matter of fact, he had just been awarded the Brofman Award of the American Public Health Association. Doctor Langmuir testified that there have been no reported cases of paralytic disease associated with Salk vaccine since 1955. (Tr. 377) He believed there was no danger in taking Salk vaccine (other than needle fright).

These things, of course, were all known to Wyeth Laboratories in 1962. Nonetheless, they went ahead with their mass immunization plan of adults.

Wyeth now claims that it warned of the risk by warning some doctors in Idaho Falls, Idaho, and that the doctors should have evaluated the risk before proceeding. Mr. Davis was not in Idaho. He was in Montana.

Wyeth knew there was no doctor in West Yellowstone, Montana (Tr. 106) They knew there would be no doctor in attendance. They knew that the clinic was going to be attended only by a pharmacist, and they knew there would be no prescription and no warning.

Even the jury was misled on this point. In Mr. Evans' closing argument to the jury he pointed out that Wyeth's

book on how to hold clinics (Plaintiff's Exhibit 26, Tr. 9) recommends strongly that a doctor be in attendance at the clinics. Mr. Evans pointed out that a doctor was present in Eastern Idaho, but at the one held in West Yellowstone, Montana, there was no doctor present. Mr. Roden objected on the grounds that there was no evidence to that effect, and the trial judge ruled as follows:

> "That is correct. The evidence does not so show. He said there was no doctor in West Yellowstone." (Tr. Vol. IV 9, L. 22-23)

The record reveals that when Mr. Davis was on the stand stand testifying he named every person who was in the room when he took the Type III polio vaccine. On page 129 of the transcript (lines 2-5) he was asked the questions:

"Was a doctor there?"

"No, sir."

"Did a doctor prescribe the vaccine for you?"

"No, sir."

The ruling and comment told the jury to the contrary, erroneously.

The Wyeth detail man, Franklin, contacted Bob Brower (the pharmacist in West Yellowstone) in January 1963, advised him that West Yellowstone was to be included in the"K. O. POLIO" campaign, found out how many doses of the vaccine to send, and subsequently sent them. (Tr. 169-171) Wyeth now claims that it did so because an Idaho doctor, Doctor Krueger, advised it to "send vaccine to West Yellowstone", (Tr. 110, L. 11) whatever that

means. Send it they did, and there is no evidence of a warning to either Brower or the people of West Yellowstone other than a package insert, unread by the pharmacis. The fact that there was a package insert does not meet the requirements of a warning. Bob Brower, the druggist who administered the vaccine in West Yellowstone, is not a doctor and cannot give medical advice and could not prescribe this vaccine for persons who wanted to take it nor could he warn of the hazards in taking it. We do not think that the package insert is even relevant unless it is related in some way to Mr. Davis or at least to a physician. However, the best that can be said for it is that it creates a jury question. Whether or not a package insert constitutes a warning is a conclusion now asserted by Wyeth trying to reinstate our cause of action on failure to warn and having this court rule as a matter of law that there was a warning. The cause should have been submitted to the jury for its determination.

The all-media propaganda program of Wyeth did not even hint at a risk. The Wyeth agent even sent a poster to West Yellowstone to be used in connection with the vaccine. (Tr. 61) The poster was devised by Wyeth. The poster said "K. O. POLIO". It has not one word about the risk in taking the Wyeth product or the fact that Wyeth knew the vaccine would cause the disease. Plaintiff relied on the poster. (Tr. 126)

It is little wonder, therefore, that when the Surgeon General's Polio Committee met in 1964 with considerable number of new personnel and reviewed the tragic histories of people such as Mr. Davis who took a product in an effort to help stamp out polio and now find them-

selves in a wheelchair that they again recommended:

> "The vaccination of individuals over school age (about 18 years) should generally be recommended only in those situations in which unusual exposure to poliomyelitis might be anticipated, such as epidemics, entry into military service, and travel to other countries." (Plaintiff's Exhibit 11)

As to findings, the Committee had 87 reported cases from non-epidemic areas. Of these, 57 were judged by the Committee to be compatible with having been induced by the vaccine. Certain other cases were classified as uncertain, and certain cases were excluded. Doctor Ravenholt commented:

> "Yes, and it also excluded quite a few cases which would ordinarily be called poliomyelitis, but would be excluded because of the rigorous conservative criteria used by the Surgeon General's Committee of a compatible case." (Tr. 489)

The compatible cases were further classified into probable and possible categories. One of the probable compatible cases was that of the plaintiff in the instant case, Glynn Richard Davis. It is little wonder that the United States Surgeon General's Committee would so find. As we all know, the defendant has the right to have the plaintiff examined by a doctor of its own choice. It elected to fly him to Los Angles, California, to be examined by Doctor Howard S. Barrows, who is a professor of neurology at the University of Southern California, School of Medicine, and one of the outstanding experts on neurology in the

United States. The concluding paragraph of his report reads as follows:

> "Despite any questions or confusion concerning dates, war injuries, work injury, possible drug addiction or alcoholism there is no doubt that this patient developed a febrile disease followed by parethesias and a progressive assymetrical motor weakness of a lower motor neuron type that has left him with an atrophic, flaccid paraplegia. The progression of his weakness stopped after the fever subsided and he had cerebrospinal fluid pleocytosis without protein elevation acutely. There apparently was muscle tenderness and nuchal rigidity. These facts on record and his present findings are, again, consistent with acute infectious poliomyelities and *not* at all suggestive of polyradiculo-neuropathy Guillain-Barre), multiple sclerosis, amytrophic lateral sclerosis, spinal cord disease, herniated disc or conversion hysteria." (Defendant's Exhibit 50) (Emphasis supplied by Dr. Barrows)

This paragraph describes a condition that the company knew it would create when it released its vaccine for sale in 1962.

Whether Wyeth had to warn Davis before they gave him the disease; whether or not giving a man polio by virtue of a product that is supposed to suppress the disease breaches a warranty of fitness to that individual; whether Wyeth is strictly liable; whether a pathogenic vaccine is a product with a defect; whether proof may be made of negligence through res ipsa loquitur; are questions that were never submitted to the jury after two weeks of trial.

The trial court deprived the jury of all legal theories except warranty of merchantability. The court's theory of the case and that of the defense was that if the defense could show that the product was reasonably fit for the public at large, they were exonerated and the plaintiff could not recover. That was the sole issue submitted to the jury and essentially, that is the sole issue the defense is trying to submit to this court on appeal. The matter is not so simple.

If the Davis injury is a cost of social progress, it is a cost that should be shared by all who benefit from the harmless use of the vaccine. The manufacturer is best able to compensate injured persons by insurance or otherwise and to distribute the cost of compensation or insurance as a typical price of the insurance by increasing the price paid by all persons who benefit from the use of the vaccine. 65 Yale Law Journal 262. Wyeth is a profit-making institution. They were producing and selling a vaccine under license from Doctor Sabin who developed it. They made a profit on the product. They knew that a certain number of people would be paralyzed as a result of taking its vaccine. We were not permitted by the judge to go into the amount of profit Wyeth made. We thought it would be an appropriate answer to their humanitarian argument, but perhaps the answer put forth in the Cutter case is sufficient, where the court said such an argument seemed to be of little weight where the warranty is limited to an assurance that the product will not actively cause the very disease it is designed to prevent. Whatever the legal theory is called, recovery should be permitted to Mr. Davis. It is now conceded all around

that he has polio because he took their vaccine. He did it at a time when the public was being urged strongly in all media of advertising to take the vaccine. In West Yellowstone, Montana, the response was overwhelming. People did this to stamp out polio. There were victims of this war. Dick Davis was one. The case should be remanded to the court below on the sole issue of damages.

Respectfully submitted

ELAM, BURKE, JEPPESEN & EVANS

by.....
Blaine F. Evans

by.....
Robert J. Koontz

by.....
Karl Jeppesen

Attorneys for Appellants

CERTIFICATE OF ATTORNEY

I certify that, in connection with the preparation of this brief, I have examined Rules 18 and 19 of the United States Court of Appeals for the Ninth Circuit, and that, in my opinion, the foregoing brief is in full compliance with those rules.

ELAM, BURKE, JEPPESEN & EVANS

by_____

Blaine F. Evans

Attorneys for Appellants

ACKNOWLEDGEMENT OF SERVICE

Service is hereby acknowledged of receipt of three (3) copies of the above and foregoing brief.

DATED: April ____, 1967.

RICHARDS, HAGA & EBERLE

by_____

Attorneys for Appellees

APPENDIX A

Doctor Ravenholt

Page 437 — Lines 6 through 22

Q Doctor, prior to the year of 1962, what was the most prevalent type of polio in the United States on important cases?

MR. RODEN: Object, as leading and suggestive, and there is no foundation for such an opinion.

THE COURT: He may answer.

THE WITNESS: There are three types of poliomyelitis—three immunological—and before the immunization, Type I was the leading type, responsible for eighty-five percent of the paralytic disease in the United States; and Type II was responsible for two or three percent; and Type III for the balance.

BY MR. KOONTZ:

Q After the introduction of the vaccine?

MR. KADING: I am going to object to further questioning. The question has been answered.

THE COURT: Objection sustained.

Page 442 — Lines 7 through 17

BY MR. KOONTZ:

Q Based on your physical examination of the plaintiff, the reports at Ashton, at Idaho Falls, and the Elks, and the Veteran's in Boise, and the laboratory reports and the history, do you have an opinion within a reasonable medicl probability what type of acute poliomyelitis he has?

A Yes.

Q What is your opinion, Doctor?

A My opinion that his poliomyelitis was in all probability caused by Type III virus—vaccine virus.
Page 442 — Lines 24 and 25

Q Doctor, upon what do you base this opinion?

A The facts that he had poliomyelitis is clearly indi-
Page 443 — Lines 1 through 13
cated by the nature of his illness, an acute feverish illness, and the central nervous infection, and accompanied by the development of severe paralysis of his lower body, which is compatible with the disease we call poliomyelitis, and not within my knowledge of any other disease. The fact that it is in all probability caused by a Type III vaccine virus is a function of the fact that his illness occurred in West Yellowstone, Montana, in the early spring when there was no known natural occurrence of polio within a wide range, and within an incubation period after takig the Sabin Type III vaccine, which is known to be able to cause paralysis in adults under these circumstances.
Page 444 — Lines 14 through 25

Q What types, generally—what are the percentages, generally, of the types of polio subsquent to 1963?

A Before the introduction of immunization, Type I was responsible for the great majority of poliomyelitis in the United States, and during the years of wide spread use of Salk vaccine, Type I was responsible gor a greater degree of the total poliomyelitis occurrences. Since the introduction of the Sabin vaccine there was a remarkable increase of the occurrenc of Type III, and it is known

that this is in all probability due to the vaccine.
Page 445 — Lines 12 through 15

Q Getting back to the question, was there any epidemiological significance after the vaccine?

A Yes. This is a new pattern of the distribution of poliomyelitis in the United States.
Page 446 — Lines 6 through 25

The Type II Sabin is probably entirely nonpathogenic and the Type I has very little capacity for the pathogenesis, and the Type III retains a virulence or pathogenicity.

Q Upon what facts do you base the statements that the Type III retains its pathogenicity?

A It was known—a measure can be obtained by studying the effect in experimental animals. The injection of the virus in the monkeys, it has been a common test of virulence and it was known.

Q You use the term "virulence"; what is that?

A That is a measure of the degree of pathogenicity. We speak of something being virulent when it has a large disease producing capacity, and it was known by the studies of Doctor Melmick in Houston in 1960 and 1961, that the Type III strain which was being used experimentally by Doctors Sabin did retain a neurovirulence for monkeys when injected. It was somewhat virulent, and there was a hesitation to releasing the vaccine because of th knowledge, and that is the reason that the Type III
Page 557 — Lines 1 through 4
was not licensed as early as Type I or Type II. Type III was not licensed until March of 1961, because there was

a waryness of its qualities. Then it was released.
Page 451 — Lines 18 through 25

BY MR. KOONTZ:

Q Doctor, do you have an opinion as to whether or not the Sabin Oral vaccine, Type III, administered in March of 1963 has a pathogenitic characteristic?

A Yes, I —

THE COURT: You have answered the question.

BY MR. KOONTZ:

Q What do you base your opinion upon?
Page 452 — Lines 1 through 9

A I base the opinion on the knowledge which had been accumulated by the United States Public Health Service by that date concerning the occurrence of paralytic poliomylitis among adults who had received Sabin Type III vaccine during the previous year and a half.

Q What is that opinion?

A It is that Type III Sabin oral vaccine remains pathogenic for adults.
Page 453 — Lines 14 through 20

Q Doctor, do you have an opinion as to whether or not in March of 1963, there was a risk in adults taking the Type III Sabin vaccine?

A Yes.

Q What is the opinion?

A It was known that it was hazardous for adults to

take Type III Sabin vaccine.

CROSS EXAMINATION

Page 457 — Lines 16 through 25

Q How much emphasis would you place on this with your conclusion that he had poliomyelitis Type III?

A Well, my understanding of this is particularly on the basis that he did have a disease which seems entirely typical of poliomyelitis to me, and Type III poliovirus was isolated repeatedly from his stool and it was vaccine like according to the Communicable Disease Center, and in this context, the history that he did take the Type III Sabin vaccine within the incubation period of his illness seems significant.

CROSS EXAMINATION

Page 473 — Lines 15 through 23

Q And the conclusion that you have to arrive at is that it is consistent with the causation of the disease by Type III, and inconsistent with it?

A If Mr. Davis had not developed poliomyelitis I would say there was no reason to think that it caused poliomyelitis. And in view of the facts that he did develop acute poliomyelitis and this was the only agent identified from him at this time, I think that it is reasonable to ascribe his illness to that agent.

CROSS EXAMINATION

Page 478 — Lines 19 through 25

Q What do you mean?

A That it occurred in late winter or early spring in West Yellowstone, Montana, independent of any other kown occurrence of poliomyelitis, and particularly Type III poliomyelitis in this community. If,for example, his illness had occurred in a mist of epidemic Type III, then it would have had a somewhat different significance.

Page 479 — Line 1

CROSS EXAMINATION

Page 479 — Lines 9 through 17

Q The fact that it occurred in West Yellowstone in March, what is the significance of the date?

A That is the time of the year when there is the least prevalence of the virus, and in 1963 there was very little prevalence of the natural virus compared with five or ten years before, and it occurred at the time of the year when the natural virus is least prevalent, and in a part of the country where it would be least prevalent.

Page 486 — Lines 11 through 19

CROSS EXAMINATION

Q Nevertheless at least in your opinion it would be intelligent to immunize susceptible people?

A We do not deem it advisable to give the oral vaccine in adults because of the availability of an excellent immunizing agent in the Salk vaccine, which at this time was not known to cause—which was rather completely devoid of any risk in adults, so why use something that is risky if you have something that is not risky.

CROSS EXAMINATION

Page 489 — Lines 16 through 24

Q The table nine does relate to the compatible cases that the Surgeon General's committee had left in the picture which by definition excluded the epidemic areas?

A Yes, and it also excluded quite a few cases which would ordinarily be called poliomyelitis, but would be excluded because of the rigorous conservative criteria used by the Surgeon General's committee of a compatible case.

CROSS EXAMINATION

Page 494 — Lines 20 through 25

THE WITNESS: If Mr. Davis had not become ill, one may have found the vaccine virus in the stool, and the antibody findings in the blood, but the fact that poliomyelitis did occur and no other organism is reasonably implicated as a cause, to me indicates that in all probability

Page 495 — Line 1

his illness was caused by the vaccine virus.

DOCTOR AGER

Page 514 — Lines 2 through 4

A My opinion is that Mr. Davis contracted acute anterior poliomyelitis from Type III poliomyelitis vaccine.

Page 517 — Lines 15 through 18

THE WITNESS: My opinion of the risk was and is that it is somewhere in the neighborhood of one in two or three thousand vaccinations of adult males.

Page 524 — Lines 17 through 23

A I will read two sentences. "After several hours of study and evidence, the committee adopted the resolutions and that it be sent to each of the state and territorial health officers, associations. Recommendation No. 2, recommended that the nonepidemic use of Type III oral vaccine be restricted to preschool and school age children."
Page 525 — Lines 5 through 7

Q In September of 1962, this had gone to all state health officers?

A That is correct.

Page 536 — Lines 1 through 11
that was made: "That there was no apparent association of cases with specific lots of vaccine and vaccines produced by a particular manufacturer". That is on the bottom of page four.

A The statement I don't think is quite accurately stated, but I do in essence agree with it. If I can clarify it for your benefit; there is a clustering with certain manufacturers and certain periods of manufacture, but these were closely related to the output of vaccine. The more doses, the more cases occurred so that company or that period of time, it balances out.

APPENDIX B

Doctor John H. Brown, Veterinarian, Assistant Vice-President of Wyeth Laboratories (Tr. 655, L. 7-25)

"BY MR. EVANS:

Q Are you familiar with a virological theory called the hot particle theory?

A Yes, sir.

Q Is this a theory generally accepted in virology?

A Yes, sir.

Q And is this particular theory applied in the field of virology to Sabin vaccine?

A Yes, sir.

Q Will you state for us what that theory is?

A The theory is applied to the Sabin vaccine and covers the following circumstances: That if in the seed used to make the vaccine, there was one hot particle of virus, which virtually, by the way that the virus is grown, and handled, that would multiply in hundreds and thousands of particles so that in the resulting vaccine there would be an abundance of hot particles, and they would be very well demonstrated in the tests we apply. And in the theory, it does not seem possible that the one hot particle situation could apply to the seed for the vaccine."

Doctor Alexander D, Langmuir, a member of the United States Surgeon General's Committee on Oral Poliomyelitis Vaccination (Tr. 379, L. 5-17)

"A I think in general there are two theories: One,

that a certain residual number of particles in the vaccine retain their virulence and in an occasional monkey are able to cause this slight degree of iflammation. The other theory is that it is a biological property of the vaccine virus to occasionally mutate to virulent form, and when this mutation occurs the frequency of the mutation, I think is quite problematic and quite controversial."

APPENDIX C

Instruction No. 13

"In this case plaintiffs seek to recover against defendants for breach of warranty.

"One of the elements of a sale of goods may be a representation or promise by the seller that the goods possess certain characteristics. Such a representation or a promise is called a warranty. It may be made expressly in so many words by the seller, or it may be implied from the circumstances of the sale. As used in these instructions, the word 'seller" includes the manufacturer of the product involved and the word 'buyer' includes the user or consumer of the product.

The law provides for implied warranties in certain cases. In this connection, I instruct you that where a buyer, expressly or by implication, makes known to the seller the particular purpose for which the goods are required, and it appears that the buyer relies on the seller's skill or judgment, whether he be the manufacturer or not, there is an implied warranty that the goods shall be reasonably fit for such purpose. If you find from a preponderance of the evidence in this case that the plaintiff Glynn Richard Davis expressly or by implication made known to the seller the particular purpose for which the vaccine was required, and you further find that the plaintiff in making this purchase relied upon the defendants' skill and judgment, then under such circumstances, there would be an implied warranty that the goods would be reasonably fit to immunize the plaintiff against the disease of poliomyelitis.

If you find and believe from a preponderance of the evidence that there was such an implied warranty on th part of the defendants as to their vaccine, and you further find that the plaintiff Glynn Richard Davis contracted the disease of poliomyelitis as a direct and proximate cause of the ingestion or taking of defendants' vaccine, then defendants would have breached their implied warranty, and you should find for the plaintiffs.

However, if you find from the evidence that there was no such implied warranty or breach thereof on the part of the defendants or that plaintiff Glynn Richard Davis did not contract poliomyelitis as a direct and proximate cause of taking defendants' vaccine, then on either or both of such findings your verdict should be for defendants."

Instruction No. 14:

"In considering the question of breach of an implied warranty, you are instructed that the implied warranty involved in this case is that the vaccine was reasonably fit for the particular purpose for which it was manufactured. In other words, under such circumstances, the law imposes upon defendants a warranty that the Sabin vaccine, which it manufactured and suppplied, was reasonably fit and reasonably safe for consumption by members of the public as a whole. This warranty does not mean, however, that this vaccine could be used with absolute safety, but means only that the vaccine must have been reasonably fit and reasonably safe for use by the public as a whole."

Instruction No. 15:

"Before you can find for the plaintiffs and against the defendants, the plaintiffs must prove by a preponderance of the evidence, the following:

That plaintiff, Glynn Richard Davis, is suffering from paralytic poliomyelitis; that he contracted this disease from defendants' Type III Sabin polio vaccine; and that he contracted the disease as a proximate result of the breach of an implied warranty of fitness, if any, on the part of the defendants."

APPENDIX D

Green v. American Tobacco Company, 325 F.2d 673 1963) p. 681; Judge Cameron concurring in part and in part dissenting.

"It would, in my opinion, be a complete rejection of the law of warranty to hold that it could abrogate the requirement that one admittedly injured by he use of tobacco could not recover unless he showed further that the cigarettes were not reasonably fit and wholesome for use by the general public. Those words are used in the warranty to demonstrate the universality of its application. Every sale it makes carries a warranty to each and every member of the public. But each warranty is separate and covers the liability of the Tobacco Company to each separate individual to whom a sale is made. The finding of the jury has settled the fact that the cigarettes sold to Green were not reasonably fit and wholesome for use by him. No other question is, in my opinion, involved under the law of Florida with which alone we are dealing."